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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,908	07/21/2003	Paul John Kawula	50623.245	5357

7590 12/30/2005

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
10/623,908	KAWULA, PAUL JOHN	
Examiner	Art Unit	
Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 9-21 and 30-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 22-29 is/are rejected.
- 7) ☒ Claim(s) 22-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/8/04, 2/17/05, 3/21/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 9-21,30-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie and invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/14/05.

Claim Objections

Claims 22-26 are objected to because of the following informalities: claim 22 is not a proper Markush type claim. The members in a Markush group (A, B, C etc.) ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. It is not clear how a plastic, metal, ceramic and glass are all considered in the same category. Claims 23-26 depend from claim 22. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3,7,8,22,23,25 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt (6099561). Fig. 2 shows the cross section of a stent **15** having a ceramic layer **80** and a drug layer **83**. Alt discloses the ceramic layer is porous (col. 10, lines 24-26) and the drug layer has an anti-inflammatory agent (col. 10, lines 36-38). Alt also discloses the surface of the stent is metal, col. 6, lines 50-55. Alt additionally discloses the stent metal can be steel or nitinol, col. 7, lines 44-49.

Claims 1-6,27 are rejected under 35 U.S.C. 102(e) as being anticipated by Hunter et al. (2004/2766). Hunter discloses (paragraph 69) that a medical implant having a metal surface has an oxide layer disposed on its surface. The examiner is interpreting the claimed elements "porous region" and "less porous region" in this way: Hunter discloses (paragraph 79) that the ceramic that is fused to the metal is firmly attached. The Examiner is interpreting this region of attachment to be less porous. The outer region or region facing away from the surface of the metal will be more porous and promote ingrowth. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055.

Claims 1-7,21,22,27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Brandau et al. (6709379). Fig. 5a shows a metal substrate layer **2**, an oxide layer **6** between the metal substrate and an outer ceramic layer **14**. Brandau discloses the implant can be a metal stent, col. 7, line 18. Brandau additionally discloses different

Art Unit: 3738

oxide layers to cover the stent, col. 8, lines 18-23. Brandau also discloses a drug **5** (col. 7, line 31) can be used with a ceramic layer, col. 8, lines 25-28. Brandau also discloses the implant can have an oxide layer and a ceramic layer, col. 3, lines 26-28. The examiner asserts that the claimed physical properties (forming the oxide/ceramic layers as having porous and less porous regions) are present in the prior art material to some extent even though they are not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24,26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt '561. Alt is explained above. Since claims 22 and 23 were met by the Examiner's finding that Alt discloses one of the Markush limitations, i.e. a metal. Claims 24,26 would be obvious to one of ordinary skill in the art as obvious variants.

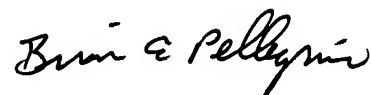
Art Unit: 3738

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (7:30am-5pm) and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738



BRIAN E. PELLEGRINO
PRIMARY EXAMINER